REMARKS

The Office action dated July 8, 2009 is acknowledged. Claims 1 – 14 are pending in the instant application. Claims 1-12 have been rejected and claims 13 and 14 have been withdrawn. By the present Office Action response, claims 1, 4 and 9 have been amended and claims 2, 3 and 8 have been canceled. Claim 1 has been amended to recite a device for transdermal administration of active substance wherein the device has a plurality of needle-shaped microprotrusions for penetrating into the skin and where the microprotrusions are helically configured and rotatably arranged to facilitate penetration into the skin by applying a rotating movement. Moreover, amended claim 1 recites that the device comprises an adhesive polymer matrix which constitutes the active substance-containing reservoir and that the reservoir is arranged on the skin side of the device coextensive with the plane of the microprotrusions. Support for amended claim 1 may be found in canceled claims 3 and 8, as well as throughout the specification. Claims 4 and 9 have been amended to depend from claim 1, rather than claims 3 and 8, respectively, which are now canceled. Reconsideration is respectfully requested in light of the arguments made herein. No new matter has been added.

Information Disclosure Statement

The Examiner notes that a few references from the Information Disclosure Statement were not considered since copies were either not filed or an English translation were not provided. Copies of GB 1315796 and NL 6614673 are submitted herewith for the Examiner's consideration. An English translation of claim 1 of NL 6614673 is also provided herewith.

Rejection of claims 1 and 2 under 35 U.S.C. 102(b)

Claims 1 and 2 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Publication No. 2002/0128599 (Cormier, et al.). The Examiner concludes that Cormier, et al. '599 disclose every limitation recited in present claims 1 and 2. In particular, the Examiner states that Cormier, et al. '599 teach a device for transdermal delivery of active agents having a backing layer and an array of barbed microprotrusions, as well as an active agent that is coated onto the microprotrusions to form a reservoir of active agent. The Examiner also states that Cormier, et al. '599 teach needle-shaped microprotrusions.

The Applicant respectfully disagrees with the Examiner's conclusion and submits that the present invention as defined in the present claims is patentably distinct from the invention disclosed in the prior art Cormier, et al. '599 reference. Cormier, et al. '599 teach a device for transdermal drug delivery, wherein the device comprises extremely tiny skin piercing elements (10). Cormier, et al. '599 also teach that the microprotrusions may be obtained by etching or punching them from a thin metal sheet and bending the microprotrusions out of the plane of the sheet (Fig. 1; paragraph [0045]). It would be clear to one skilled in the art that those microprotrusions are neither helically configured nor rotatably arranged as presently claimed. In addition, Cormier, et al. '599 do not teach or suggest any embodiment of their transdermal drug device which may comprise helically configured or rotatably arranged microprotrusions. Therefore, the present claims are clearly not anticipated by Cormier, et al. '599. Withdrawal of the present rejection is respectfully requested.

Rejection of claims 1, 2 and 5-7 under 35 U.S.C. 102(e)

Claims 1, 2 and 5-7 have been rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Publication No. 2004/0106904 (Gonnelli, et al.). The Examiner concludes that Gonnelli, et al. disclose every limitation recited in present claims 1, 2 and 5-7. In particular, the Examiner states that Gonnelli, et al. teach a microneedle device for the transport of drug molecule across tissue, having an embodiment wherein an array of hollow microneedles are attached to a housing containing drug in an internal reservoir and comprising a backing layer. The Examiner also states that Gonnelli, et al. teach that the microneedles may comprise plugs having barbs to catch biological tissue and that the plugs on the microneedles may have a cone or arrowhead shape to form barbed ends for gripping biological tissue.

The Applicant respectfully disagrees with the Examiner's conclusion and submit that the present invention as defined in the present claims is patentably distinct from the invention disclosed in the prior art Gonnelli, et al. reference. Gonnelli, et al. teach microneedle devices for transport of molecules across tissue. The microneedles permit drug delivery or removal of body fluids across the skin. The microneedles are thus hollow microneedles and may comprise a plugging element in the form of a platform including a plurality of microneedle plugs for preventing skin or tissue barriers from entering the hollow microneedles (Abstract; Fig. 5A).

Gonnelli, et al. do not teach that the microneedles are helically configured or rotatably arranged. Therefore, the present claims are clearly not anticipated by Cormier,

et al. Withdrawal of the present rejection is respectfully requested.

Rejection of claims 1-12 under 35 U.S.C. 103(a)

Claims 1, 3 and 4 have been rejected as being unpatentable over U.S. Publication No. 2005/0137525 (Wang, et al.) in view of U.S. Publication No. 2005/0118388 (Kingsford). The Examiner states that Wang, et al. disclose rotating microneedle arrays that drill holes into a biological barrier, such as skin, which can be used for transdermal penetration by rotating the microneedles. The Examiner also states that Wang, et al. teach that the microneedles can be driven by pneumatic or hydraulic actuators and the attachment of the microneedles to a reservoir. However, the Examiner acknowledges that Wang, et al. fail to teach a backing layer. In this regard, the Examiner's position is that it would have been obvious to one skilled in the art to provide the device of Wang, et al. with a backing layer as it is typical in the art as taught by Kingsford to provide support for the device. Therefore, the Examiner concludes that the combination of teachings of Wang, et al. and Kingsford render claims 1, 3 and 4 obvious.

Claims 1, 2 and 5-12 have been rejected as being unpatentable over Gonnelli, et al. in view of U.S. Patent No. 6,656,147 (Gertsek, et al.) and U.S. Publication No. 2002/0016562 (Cormier, et al.). The Examiner states that Gonnelli, et al. disclose the limitations of these claims, as discussed above, except for a polymer adhesive. The Examiner refers to Gertsek, et al. for teaching a microneedle device for delivering a substance into the skin and that the bottom surface of the device housing can comprise a pressure sensitive adhesive which can be a suitable adhesive known in the art of adhesive bandages. Thus, the Examiner concludes it would be clear to one skilled in the art that

polymeric adhesives (i.e., pressure-sensitive adhesive polymers) are commonly used in such applications.

The Examiner also states that Gonnelli, et al. fail to teach the placement of active substances in the adhesive layer but concludes that this would be obvious to one skilled in the art. The Examiner refers to Cormier, et al. '562 for disclosing transdermal delivery devices comprising a plurality of microprotrusions for anchoring to the skin and delivery of active agents. The Examiner also states that Cormier, et al. '562 teach the use of adhesives, as well as that the adhesive may contain an active agent. The Examiner concludes that it would have been obvious for one skilled in the art to include an active agent in the adhesive layer of Gonnelli, et al. to provide a reservoir in close proximity to the sites of microneedle puncture. Therefore, the Examiner concludes that the combination of teachings of these references render claims 1, 2 and 5-12 obvious.

The Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The Applicant respectfully submits that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider the teachings of the cited prior art alone or in combination, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the

aforementioned references were to be considered.

The Applicant respectfully disagrees with the Examiner's conclusion. Wang, et al. teach rotating microneedles and microneedle arrays that drill holes into a biological barrier such as the skin. The holes are suitable for the administration of drugs. The microneedle array of Wang, et al. does not comprise an adhesive polymer matrix which constitutes the active substance-containing reservoir. For the administration of drugs, the device of Wang, et al. requires the connection of microneedles to a fluid reservoir such as a syringe (Fig. 3; paragraph [0065]; Fig. 22; paragraph [0088]; paragraphs [0115] – [0117]). Wang, et al. also do not indicate that their device might be suitable for the administration of a drug that is incorporated into a polymeric matrix and is released by diffusion rather than being forced into the hole by means of a syringe.

Kingsford fails to make up for the deficiencies of Wang, et al. Kingsford may teach skin attachment members comprising retaining elements and a backing. The retaining members may be provided with bars, but the retaining members are not rotatable. For drug delivery, the retaining elements or penetrating elements are provided with longitudinal grooves which provide passage for drug delivery (paragraph [0038]). One skilled in the art would readily recognize that the drug to be delivered has to be present in liquid form so that it can pass along the longitudinal grooves. Moreover, Kingsford does not teach devices comprising an adhesive polymer matrix which constitutes an active substance-containing reservoir and is arranged on the skin side.

Thus, the Applicant submits that the combined teachings of Wang, et al. and Kingsford fail to teach providing a microneedle device with an adhesive polymer matrix

which constitutes an active substance-containing reservoir, and which is arranged on the skin side of the device. Therefore, each and every limitation of the presently claimed invention is not taught or disclosed by the combination of teachings of Wang, et al. in view of Kingsford and so the combination fails to render the presently claimed invention obvious. Withdrawal of this rejection is requested.

The Applicant also respectfully disagrees with the Examiner's conclusion for at least the deficiencies of Gonnelli, et al. discussed above. Gertsek, et al. fail to make up for the deficiencies of Gonnelli, et al. Gertsek, et al. teach a delivery device for transdermal administration of a substance wherein the device comprises a plurality of hollow microneedles for penetrating the skin which become connected to the lumen of a bladder by means of a cannula. The cannula punctures the bladder and the fluid within the bladder can be pressed from the bladder through the microneedles into the patient's skin.

The Applicant submits that the combined teachings of Gonnelli, et al. and Gertsek, et al. do not teach providing a drug delivery device comprising microneedles with an adhesive polymer matrix which constitutes an active substance-containing reservoir, and which is arranged on the skin side such that the active substance can permeate into the skin. In addition, the combination of these prior art reference does not teach to configure the microneedles helically and to arrange them rotatably, as recited in present claim 1.

Cormier, et al. '562 fail to make up for the deficiencies of Gonnelli, et al. Cormier, et al. '562 teach a percutaneous agent delivery or sampling device comprising a

sheet having a plurality of microblades for piercing and anchoring to the skin for increasing transdermal flux of an agent. Referring to Figures 26 – 28 therein, the device of Cormier, et al. '562 may comprise an adhesive overlay (100) and/or a reservoir (90). In contrast to the presently claimed invention, the adhesive overlay (100) is not the active substance-containing reservoir. Neither the adhesive overlay nor the reservoir is arranged on the skin side coextensive with the plane of the microprotrusions. Instead, they are arranged on the side of the anchoring elements facing away from the skin. Moreover, Cormier, et al. '562 do not teach to configure the microneedles helically and to arrange them rotatably. Thus, the combined teachings of Gonnelli, et al, in view of Gertsek, et al. and Cormier, et al. '562 fail to teach each and every limitation of the presently claimed invention, and thus fail to render the presently claimed invention obvious.

In view of the above, it is clear that one skilled in the art would not be motivated to combine the teachings of said references or to modify the cited prior art references to arrive at the presently claimed invention. Even if one were to do so, each and every limitation of the presently claimed invention would not be taught or disclosed. Therefore, the Applicant respectfully requests that the obviousness rejections be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the anticipation and obviousness-type rejections be withdrawn. The Examiner is invited to call the undersigned if there are any

remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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